

R E M A R K S

Claims 1, 3 to 5, 10 to 13, 15 to 21 and 23 to 25 as set forth in Appendix II of this paper are now pending in this case. Claim 2 has been canceled and Claims 1, 3 to 5, 10 to 13, 15 to 21 and 23 to 25 have been amended as indicated in the Listing of Claims set forth in Appendix I of this paper.

Accordingly, applicants have specified the polyether-containing compounds referenced in (A)b) of Claims 1 and 5 in accordance with the provisions of Claim 2 and Claim 2 has been canceled. Additionally, applicants have introduced the expression --shell-- after "hard capsule" throughout the claims¹⁾, and have made some editorial changes in the wording of Claims 17, 20 and 21. No new matter has been added.

The Examiner has rejected Claims 1 to 5, 10 to 13, 15 to 21 and 23 to 25 under 35 U.S.C. §112, ¶2, as being indefinite. More particularly the Examiner contends that it is unclear whether the polymers specified in the claims are part of the capsule shell or part of a filling.

The test of definiteness under 35 U.S.C. §112, ¶2, is whether a person of ordinary skill in the art would understand the meets and bounds of the claim when reading the claim in the light of the specification supporting it²⁾. Already in the introductory remarks³⁾ applicants specification makes it clear that the expression "hard capsules" is used in the context of the invention as a synonym for the shells⁴⁾. A person of ordinary skill reading the claims in light of the supporting specification would therefore not be in doubt whether the polymer specified in applicants' claims is to be part of the

1) The expression "shell" is, for example, used by applicants on page 25, indicated lines 6 to 9, of the application.

2) Morton Int. Inc. v. Cardinal Chem. Co., 5 F.3d 1464, 28 USPQ2d 1190 (CAFC 1993); Orthokinetics Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1 USPQ2d 1081 (CAFC 1986)

3) Note pages 1 to 4 of the application.

4) Note in particular page 1, indicated lines 13 to 15 and indicated lines 37 to 40, in conjunction with page 3, indicated lines 40 to 43, page 24, indicated lines 16 to 38, and page 25, indicated lines 6 to 9, of the application.

shell or part of the filling. As such, the examiner's position does not appear to be well taken.

In light of the foregoing remarks and the revisions effected in the claim language it is therefore respectfully requested that the rejection under Section 112, ¶2, be withdrawn. Favorable action is solicited.

The Examiner has rejected Claims 1 to 5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable in light of Claims 1 to 19 of *Götsche et al.* (US 6,579,953).

Applicants herewith submit a terminal disclaimer disclaiming the terminal part of a patent granted on this application which would extend beyond the expiration date of US 6,579,953, and agreeing that a patent granted on this application shall be enforceable only for and during such period that the legal title of such patent is the same as the legal title to US 6,579,953. Withdrawal of the rejection under the judicially created doctrine of obviousness-type double patenting is therefore respectfully solicited.

The Examiner has rejected Claims 1, 5, 10 to 13, 15 to 21 and 23 to 25 under 35 U.S.C. §112, ¶1, contending that the scope of enablement which is provided by the specification concerning polyether-containing compounds does not extend beyond the scope of formula I as defined in Claim 2.

Applicants have introduced formula I and the definition thereof set forth in Claim 2 into Claims 1 and 5. Claims 10 to 13, 15 to 21 and 23 to 25 depend directly or indirectly upon Claim 1 so that those dependent claims incorporate the respective formula and definition by reference. Favorable reconsideration of the Examiner's position and withdrawal of the rejection under Section 112, ¶1, is therefore respectfully solicited.

In light of the foregoing and the attached, the application should now be in condition for allowance. Favorable action is solicited.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees, to Deposit Account No. 11.0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

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Encl.: THE LISTING OF CLAIMS (Appendix I)
THE CURRENT CLAIMS (Appendix II)
Therminial Disclaimer concerning *US 6,579,953*

HBK/BAS

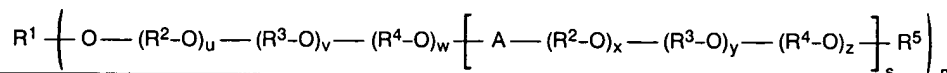
A P P E N D I X I:

THE LISTING OF CLAIMS (version with markings):

1. (currently amended) A hard capsule shell comprising

(A) polymers produced by free-radical polymerization of

- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
- b) polyether-containing compounds of formula I



in which the variables have, independently of one another, the following meaning:

R¹ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-, poly-alcohol residue;

R⁵ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

R² to R⁴ -(CH₂)₂-, -(CH₂)₃-, -(CH₂)₄-, -CH₂-CH(R⁶)-, -CH₂-CHOR⁷-CH₂-;

R⁶ C₁-C₂₄-alkyl;

R⁷ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

A -C(=O)-O-, -C(=O)-B-C(=O)-O-, -C(=O)-NH-B-NH-C(=O)-O-;

B -(CH₂)_t-, arylene, optionally substituted;

n 1 to 1000;

s 0 to 1000;

t 1 to 12;

u 1 to 5000;

v 0 to 5000;

w 0 to 5000;

x 0 to 5000;

y 0 to 5000;

z 0 to 5000;

and

- c) at least one other copolymerizable monomer c) selected from the group consisting of tert-butyl acrylate, methyl methacrylate, ethyl methacrylate, isobutyl acrylate, tert-butyl methacrylate, styrene, vinyl chloride, acrylic acid, methacrylic acid, acrylamide and methacrylamide,

and subsequent at least partial hydrolysis of the ester functions in the original monomers a),

(B) optionally, structure-improving auxiliaries and

(C) optionally other constituents selected from the group consisting of fillers, release agents, flow aids, stabilizers, water-soluble or water-insoluble dyes, flavorings and sweeteners.

2. (canceled)

3. (currently amended) A hard capsule shell as claimed in claim 1, wherein the polymers (A) are obtained by free-radical polymerization of

a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of

b) polyether-containing compounds of the general formula I with a number average molecular weight of from 300 to 100,000, in which the variables have, independently of one another, the following meaning:

R¹ hydrogen, C₁-C₁₂-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-, polyalcohol residue;

R⁵ hydrogen, C₁-C₁₂-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

R² to R⁴ -(CH₂)₂-, -(CH₂)₃-, -(CH₂)₄-, -CH₂-CH(R⁶)-, -CH₂-CHOR⁷-CH₂-;

R⁶ C₁-C₁₂-alkyl;

R⁷ hydrogen, C₁-C₁₂-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

n 1 to 8;

s 0;

u 2 to 2000;

v 0 to 2000;

w 0 to 2000;

and

c) at least one or more other copolymerizable monomers selected from the group consisting of tert-butyl acrylate, methyl methacrylate, ethyl methacrylate, isobutyl acrylate, tert-butyl methacrylate, styrene, vinyl chloride, acrylic acid, methacrylic acid, acrylamide and methacrylamide,

and subsequent at least partial hydrolysis of the ester functions in the original monomers a).

4. (currently amended) A hard capsule shell as claimed in claim 1, wherein the polymers (A) are obtained by free-radical polymerization of

- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
- b) polyether-containing compounds of the general formula I with a number average molecular weight of from 500 to 50,000, in which the variables have, independently of one another, the following meaning:

R¹ hydrogen, C₁-C₆-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

R⁵ hydrogen, C₁-C₆-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

R² to R⁴ -(CH₂)₂-, -(CH₂)₃-, -(CH₂)₄-, -CH₂-CH(R⁶)-, -CH₂-CHOR⁷-CH₂-;

R⁶ C₁-C₆-alkyl;

R⁷ hydrogen, C₁-C₆-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

n 1;

s 0;

u 5 to 1000;

v 0 to 1000;

w 0 to 1000;

and

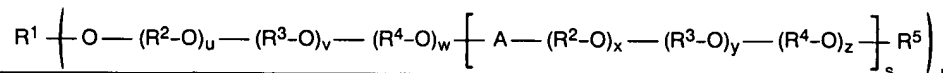
- c) one or more other copolymerizable monomers selected from the group consisting of tert-butyl acrylate, methyl methacrylate, ethyl methacrylate, isobutyl acrylate, tert-butyl methacrylate, styrene, vinyl chloride, acrylic acid, methacrylic acid, acrylamide and methacrylamide,

and subsequent at least partial hydrolysis of the ester functions in the original monomers a).

5. (currently amended) A hard capsule shell as claimed in claim 1, wherein the polymers (A) are obtained by free-radical polymerization of

- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of

- b) polyether-containing compounds of formula I



in which the variables have, independently of one another, the following meaning:

R¹ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-, polyalcohol residue;

R⁵ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

R² to R⁴ -(CH₂)₂-, -(CH₂)₃-, -(CH₂)₄-, -CH₂-CH(R⁶)-, -CH₂-CHOR⁷-CH₂-;

R⁶ C₁-C₂₄-alkyl;

R⁷ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

A -C(=O)-O-, -C(=O)-B-C(=O)-O-, -C(=O)-NH-B-NH-C(=O)-O;

B -(CH₂)_n-, arylene, optionally substituted;

n 1 to 1000;

s 0 to 1000;

t 1 to 12;

u 1 to 5000;

v 0 to 5000;

w 0 to 5000;

x 0 to 5000;

y 0 to 5000;

z 0 to 5000;

and

- c) at least one other copolymerizable monomer selected from the group consisting of tert-butyl acrylate, methyl methacrylate, ethyl methacrylate, isobutyl acrylate, tert-butyl methacrylate, styrene, vinyl chloride, acrylic acid, methacrylic acid, acrylamide and methacrylamide,

and subsequent at least partial hydrolysis of the ester functions in the original monomers a), wherein the polyether-containing compounds b) have been prepared by polymerization of ethylenically unsaturated alkylene oxide-containing monomers, alone or together with, other copolymerizable monomers.

6. (canceled)

7. (canceled)

8. (canceled)

9. (canceled)

10. (currently amended) A hard capsule shell as claimed in claim 1, wherein the resulting polymers are subsequently crosslinked.
11. (currently amended) A hard capsule shell as claimed in claim 10, wherein the resulting polymers are subsequently crosslinked by reaction with one or more compounds selected from the group consisting of dialdehydes, diketones, dicarboxylic acids, boric acid, boric acid salts, and salts of multiply charged cations.
12. (currently amended) A hard capsule shell as claimed in claim 1, wherein the structure-improving auxiliaries (B) employed are selected from the following classes of compounds:
 - a) polymers with a molecular weight greater than 50,000
 - b) substances which lead to crosslinking of the polymer chains of the polymers,
 - c) and substances which lead to crosslinking of the polymer chains of the structure-improving auxiliaries.
13. (currently amended) A hard capsule shell as claimed in claim 1, wherein the structure-improving auxiliaries employed are polymers selected from the group consisting of: polyamino acids, polysaccharides and synthetic polymers.
14. (canceled)
15. (currently amended) A hard capsule shell as claimed in claim 1, wherein the capsule consists of 10 to 100% polymers of vinyl esters on polyether, 0 to 80% structure-improving auxiliaries and 0 to 30% said other constituents.
16. (currently amended) A hard capsule shell according to claim 1, obtained by the dip process.
17. (currently amended) A hard capsule shell as claimed in claim 1 which ~~[has been packed with]~~ encapsulates ingredients selected from the group consisting of one or more active pharmaceutical ingredients, vitamins, carotenoids, minerals, trace elements, food supplements, cosmetic active ingredients, crop protection agents, bath additives, perfume, flavoring, cleaner and detergent.
18. (currently amended) A hard capsule shell as claimed in claim 1 which capsule comprises from 20 to 80% of a polymer resistant to gastric fluid.

19. (currently amended) A hard capsule shell as claimed in claim 18, wherein said polymer resistant to gastric fluid is applied as a coating using pharmaceutical coating processes.
20. (currently amended) The hard capsule shell as claimed in claim 17 which [~~contains~~] encapsulates one or more pharmaceutical ingredients.
21. (currently amended) The hard capsule shell as claimed in claim 17 which [~~contains~~] encapsulates one or more ingredients selected from the group consisting of cosmetics, crop protection agents, cleaning agents and food supplements.
22. (canceled)
23. (currently amended) A hard capsule shell as claimed in claim 13, wherein said polyamino acids are selected from the group consisting of gelatin, zein, soybean protein and derivatives thereof.
24. (currently amended) A hard capsule shell as claimed in claim 13, wherein said polysaccharides are selected from the group consisting of starch, degraded starch, maltodextrins, carboxymethylstarch, cellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylcellulose, carboxymethylcellulose, ethylcellulose, cellulose acetate, cellulose acetate phthalate, hydroxypropylcellulose acetate phthalate, hydroxypropylcellulose acetate succinate, hemicellulose, galactomannans, pectins, alginates, carrageenans, xanthan, gellan, dextran, curdlan, pullulan, gum arabic, chitin, and derivatives thereof.
25. (currently amended) A hard capsule shell as claimed in claim 13, where said synthetic polymers are selected from the group consisting of polyacrylic acid, polymethacrylic acid, copolymers of acrylic esters and methacrylic esters, polyvinyl alcohols, polyvinyl acetate, polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, polyvinylpyrrolidones and derivatives thereof.

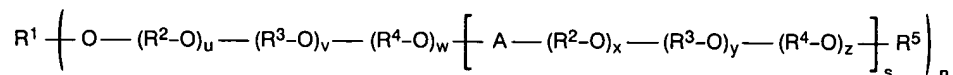
A P P E N D I X II:

THE CURRENT CLAIMS (clean version):

1. (currently amended) A hard capsule shell comprising

(A) polymers produced by free-radical polymerization of

- a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of
- b) polyether-containing compounds of formula I



in which the variables have, independently of one another, the following meaning:

R¹ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-, poly-alcohol residue;

R⁵ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

R² to R⁴ -(CH₂)₂-, -(CH₂)₃-, -(CH₂)₄-, -CH₂-CH(R⁶)-, -CH₂-CHOR⁷-CH₂-;

R⁶ C₁-C₂₄-alkyl;

R⁷ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

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B -(CH₂)_t-, arylene, optionally substituted;

n 1 to 1000;

s 0 to 1000;

t 1 to 12;

u 1 to 5000;

v 0 to 5000;

w 0 to 5000;

x 0 to 5000;

y 0 to 5000;

z 0 to 5000;

and

- c) at least one other copolymerizable monomer c) selected from the group consisting of tert-butyl acrylate, methyl methacrylate, ethyl methacrylate, isobutyl acrylate, tert-butyl methacrylate, styrene, vinyl chloride, acrylic acid, methacrylic acid, acrylamide and methacrylamide,

and subsequent at least partial hydrolysis of the ester functions in the original monomers a),

(B) optionally, structure-improving auxiliaries and

(C) optionally other constituents selected from the group consisting of fillers, release agents, flow aids, stabilizers, water-soluble or water-insoluble dyes, flavorings and sweeteners.

2. (canceled)

3. (currently amended) A hard capsule shell as claimed in claim 1, wherein the polymers (A) are obtained by free-radical polymerization of

a) at least one vinyl ester of C₁-C₂₄-carboxylic acids in the presence of

b) polyether-containing compounds of the general formula I with a number average molecular weight of from 300 to 100,000, in which the variables have, independently of one another, the following meaning:

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R⁶ C₁-C₁₂-alkyl;

R⁷ hydrogen, C₁-C₁₂-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

n 1 to 8;

s 0;

u 2 to 2000;

v 0 to 2000;

w 0 to 2000;

and

c) at least one or more other copolymerizable monomers selected from the group consisting of tert-butyl acrylate, methyl methacrylate, ethyl methacrylate, isobutyl acrylate, tert-butyl methacrylate, styrene, vinyl chloride, acrylic acid, methacrylic acid, acrylamide and methacrylamide,

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R⁷ hydrogen, C₁-C₆-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;

n 1;

s 0;

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v 0 to 1000;

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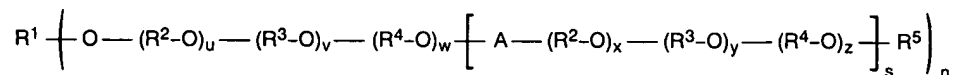
and

- c) one or more other copolymerizable monomers selected from the group consisting of tert-butyl acrylate, methyl methacrylate, ethyl methacrylate, isobutyl acrylate, tert-butyl methacrylate, styrene, vinyl chloride, acrylic acid, methacrylic acid, acrylamide and methacrylamide,

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- R⁷ hydrogen, C₁-C₂₄-alkyl, R⁶-C(=O)-, R⁶-NH-C(=O)-;
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- B -(CH₂)_t-, arylene, optionally substituted;
- n 1 to 1000;
- s 0 to 1000;
- t 1 to 12;
- u 1 to 5000;
- v 0 to 5000;
- w 0 to 5000;
- x 0 to 5000;
- y 0 to 5000;
- z 0 to 5000;

and

- c) at least one other copolymerizable monomer selected from the group consisting of tert-butyl acrylate, methyl methacrylate, ethyl methacrylate, isobutyl acrylate, tert-butyl methacrylate, styrene, vinyl chloride, acrylic acid, methacrylic acid, acrylamide and methacrylamide,

and subsequent at least partial hydrolysis of the ester functions in the original monomers a), wherein the polyether-containing compounds b) have been prepared by polymerization of ethylenically unsaturated alkylene oxide-containing monomers, alone or together with, other copolymerizable monomers.

6. (canceled)
7. (canceled)
8. (canceled)
9. (canceled)

10. (currently amended) A hard capsule shell as claimed in claim 1, wherein the resulting polymers are subsequently crosslinked.
11. (currently amended) A hard capsule shell as claimed in claim 10, wherein the resulting polymers are subsequently crosslinked by reaction with one or more compounds selected from the group consisting of dialdehydes, diketones, dicarboxylic acids, boric acid, boric acid salts, and salts of multiply charged cations.
12. (currently amended) A hard capsule shell as claimed in claim 1, wherein the structure-improving auxiliaries (B) employed are selected from the following classes of compounds:
 - a) polymers with a molecular weight greater than 50,000
 - b) substances which lead to crosslinking of the polymer chains of the polymers,
 - c) and substances which lead to crosslinking of the polymer chains of the structure-improving auxiliaries.
13. (currently amended) A hard capsule shell as claimed in claim 1, wherein the structure-improving auxiliaries employed are polymers selected from the group consisting of: polyamino acids, polysaccharides and synthetic polymers.
14. (canceled)
15. (currently amended) A hard capsule shell as claimed in claim 1, wherein the capsule consists of 10 to 100% polymers of vinyl esters on polyether, 0 to 80% structure-improving auxiliaries and 0 to 30% said other constituents.
16. (currently amended) A hard capsule shell according to claim 1, obtained by the dip process.
17. (currently amended) A hard capsule shell as claimed in claim 1 which encapsulates ingredients selected from the group consisting of one or more active pharmaceutical ingredients, vitamins, carotenoids, minerals, trace elements, food supplements, cosmetic active ingredients, crop protection agents, bath additives, perfume, flavoring, cleaner and detergent.
18. (currently amended) A hard capsule shell as claimed in claim 1 which capsule comprises from 20 to 80% of a polymer resistant to gastric fluid.

19. (*currently amended*) A hard capsule shell as claimed in claim 18, wherein said polymer resistant to gastric fluid is applied as a coating using pharmaceutical coating processes.
20. (*currently amended*) The hard capsule shell as claimed in claim 17 which encapsulates one or more pharmaceutical ingredients.
21. (*currently amended*) The hard capsule shell as claimed in claim 17 which encapsulates one or more ingredients selected from the group consisting of cosmetics, crop protection agents, cleaning agents and food supplements.
22. (*canceled*)
23. (*currently amended*) A hard capsule shell as claimed in claim 13, wherein said polyamino acids are selected from the group consisting of gelatin, zein, soybean protein and derivatives thereof.
24. (*currently amended*) A hard capsule shell as claimed in claim 13, wherein said polysaccharides are selected from the group consisting of starch, degraded starch, maltodextrins, carboxymethylstarch, cellulose, hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylcellulose, carboxymethylcellulose, ethylcellulose, cellulose acetate, cellulose acetate phthalate, hydroxypropylcellulose acetate phthalate, hydroxypropylcellulose acetate succinate, hemicellulose, galactomannans, pectins, alginates, carrageenans, xanthan, gellan, dextran, curdlan, pullulan, gum arabic, chitin, and derivatives thereof.
25. (*currently amended*) A hard capsule shell as claimed in claim 13, where said synthetic polymers are selected from the group consisting of polyacrylic acid, polymethacrylic acid, copolymers of acrylic esters and methacrylic esters, polyvinyl alcohols, polyvinyl acetate, polyethylene glycols, polyoxyethylene/polyoxypropylene block copolymers, polyvinylpyrrolidones and derivatives thereof.